Sacituzumab Tirumotecan (MK-2870) Versus Chemotherapy in Previously Treated Advanced or Metastatic Nonsquamous Non-small Cell Lung Cancer (NSCLC) With EGFR Mutations or Other Genomic Alterations (MK-2870-004)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

The main inclusion and exclusion criteria include but are not limited to the following:

Inclusion Criteria:

* Histologically- or cytologically-documented advanced (Stage III not eligible for resection or curative radiation) or metastatic non-squamous NSCLC with specific mutations. * Documentation of locally assessed radiological disease progression while on or after last treatment based on Response Evaluation Criteria in Solid Tumors Version (RECIST) 1.1. * Participants with genome mutations must have received 1 or 2 prior lines of epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI), including a third generation TKI for participants with a T790M mutation; and 1 platinum-based therapy after progression on or after EGFR TKI. * Measurable disease per RECIST 1.1 as assessed by the local site investigator. * Archival tumor tissue sample or newly obtained core, incisional, or excisional biopsy of a tumor lesion not previously irradiated has been provided * Participants who have AEs due to previous anticancer therapies must have recovered to Grade ≤1 or baseline. * Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received HBV antiviral therapy for at least 4 weeks, and have undetectable HBV viral load prior to randomization. * Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy. * Have an ECOG performance status of 0 or 1 within 3 days before randomization.

Exclusion Criteria:

* Has predominantly squamous cell histology NSCLC. * Has mixed tumor(s) with small cell elements. * Has active inflammatory bowel disease requiring immunosuppressive medication or previous history of inflammatory bowel disease. * Has Grade ≥2 peripheral neuropathy. * Has history of documented severe dry eye syndrome, severe Meibomian gland disease and/or blepharitis, or corneal disease that prevents/delays corneal healing. * Has uncontrolled, significant cardiovascular disease or cerebrovascular disease. * Has an EGFR T790M mutation and has not received a third generation EGFR TKI (eg, osimertinib). * Received prior systemic anticancer therapy including investigational agents within 4 weeks or 5 half-lives (whichever is shorter) before randomization. * Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. * Completed palliative radiotherapy within 7 days of the first dose. Participants must have recovered from all radiation-related toxicities and not require corticosteroids. * Received radiation therapy to the lung that is \>30 Gy within 6 months of the first dose of study intervention. * Received prior treatment with a trophoblast cell-surface antigen 2 (TROP2)-targeted antibody-drug conjugate (ADC). * Received prior treatment with a topoisomerase I-containing ADC. * Has received an investigational agent or has used an investigational device within 4 weeks prior to study intervention administration. * Known additional malignancy that is progressing or has required active treatment within the past 3 years. * Active infection requiring systemic therapy. * History of noninfectious pneumonitis/ILD that required steroids or has current pneumonitis/ILD. * Has known active central nervous system metastases and/or carcinomatous meningitis. Participants with previously treated brain metastases may participate provided they are clinically stable, radiologically stable for at least 4 weeks and do not require glucocorticoids for at least 14 days prior to randomization. * HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease. * Concurrent active Hepatitis B (defined as HBsAg positive and/or detectable HBV DNA) and Hepatitis C virus (defined as anti-HCV Ab positive and detectable HCV RNA) infection.

Conditions & Interventions

Interventions:
BIOLOGICAL: Sacituzumab tirumotecan, DRUG: Docetaxel, DRUG: Pemetrexed
Conditions:
Non-small Cell Lung Cancer (NSCLC)
Keywords:
Anaplastic lymphoma kinase (ALK), Antibody-drug conjugate (ADC), Epidermal growth factor receptor (EGFR), Trophoblast cell-surface antigen 2 (TROP2)

More Information

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Phase: PHASE3
IRB
Number:
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